# **EXHIBIT E**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY **CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

All Actions

Civ. No. 19-2875 (RBK/JS)

PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION TO TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS, LLC, ARROW PHARM MALTA LTD., AND ACTAVIS PHARMA, INC. PURSUANT TO FED. R. CIV. P. 30(b)(6)

Lori Cohen, Esq. Greenberg Traurig, LLP Terminus 200 Building, 25th Floor 3333 Piedmont Road NE Atlanta, Georgia 30305

> Counsel for Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc.

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this \_\_26<sup>th</sup> day of November October, 2020.

# MAZIE SLATER KATZ & FREEMAN, LLC

By: /s/ Adam M. Slater

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Attorneys for Plaintiffs

#### **CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on October 26, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc., and Defendants' liaison counsel, via email.

DATED this \_\_\_26<sup>th</sup> day of November October, 2020.

# MAZIE SLATER KATZ & FREEMAN, LLC

By: /s/ Adam M. Slater

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#### **EXHIBIT A**

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All topics reference information and documents known to, and/or in the possession, custody, or control, of Teva, in the ordinary course of its business.

All references to Teva include Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc.

All references to ZHP'S valsartan API, or ZHP's API are defined to include the valsartan API manufactured, sold, or distributed by ZHP for sale in the United States.

All references to Mylan's valsartan API, or Mylan's API are defined to include the valsartan API manufactured, sold, or distributed by Mylan for sale in the United States.

All references include all legacy entities (such as Actavis or Arrow entities in Malta) that purchased valsartan API and sold valsartan finished dose intended for <u>use-sale</u> in the United States.

All references to the finished dose or Teva's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Teva for sale in the United States.

All references to testing are defined to include testing capable of detecting impurities such as nitrosamines and contents of API or finished dose, and include but are not limited to the followingAll references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Teva's valsartan finished dose manufactured for sale in the United States (including testing of ZHP and Mylan valsartan API utilized to manufacture Teva's valsartan finished dose), and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)

- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

#### Testing of Valsartan API and Finished Dose

The cause of the contamination of ZHP's valsartan API with nitrosamines including 1.

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- 2. The cause of the contamination of Mylan's valsartan API with nitrosamines including NDMA.
- The root cause investigation for the nitrosamine impurities, including NDMA and NDEA 3. in the ZHP API.
- The root cause investigation for the nitrosamine impurities, including NDMA and NDEA 4. in the Mylan API.
- 5. The testing performed by Teva or its agents, to evaluate the purity and contents of ZHP's API used to manufacture finished dose products for sale in the United States.
- The testing performed by Teva or its agents, to evaluate the purity and contents of 6. Mylan's API used to manufacture finished dose products for sale in the United States.
- 7. The testing performed by Teva or its agents, to evaluate the purity and contents of Teva's finished dose (regardless of intended sale location) used to manufacture finished dose products for sale in the United States, manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
- The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of ZHP's valsartan API.
- The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of Mylan's valsartan API.
- The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of Teva's finished dose (regardless of intended sale location) used to manufacture finished dose products for sale in the United States, manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
- The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of ZHP's valsartan API used to manufacture finished dose products for sale in the
- 12.10. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of Mylan's valsartan API used to manufacture finished dose products for sale in the United States.
- The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of Teva's finished dose used to manufacture finished dose products for sale in the United States, (regardless of intended sale location) manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
- The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of ZHP's valsartan API.
- The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of Mylan's valsartan API.
- 16.12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of Teva's finished dose (regardless of intended sale location) manufactured for sale in the United States, manufactured in any facility that manufactured Teva's finished dose for sale in the United States.

Commented [SH1]: To the extent this would possibly be relevant is covered by No. 1 and No. 2 above

Commented [AS2]: No further clarification of the scope of the testing at issue is necessary since the testing is already defined above.

- 47.13. Teva's evaluation of the potential risks to the purity or contents of ZHP's API posed or caused by solvents used during the ZHP API manufacturing process used to manufacture finished dose products for sale in the United States.
- 18.14. Teva's evaluation of the potential risks to the purity or contents of Mylan's API posed or caused by solvents used during the Mylan API manufacturing process used to manufacture finished dose products for sale in the United States.
- Teva's evaluation of the potential risks to the purity or contents of Teva's finished dose posed or caused by solvents used during the Teva finished dose manufacturing process (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. .
- The chromatogram and mass spectrometry or other results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API.
- The chromatogram and mass spectrometry or other results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan API.
- The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of the solvents utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
- The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to Teva, of the solvents utilized in the manufacture of ZHP's API.
- The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Mylan or its agents but known to Teva, of the solvents utilized in the manufacture of Mylan's API.
- The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of the solvents utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
- 26.15. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of the production equipment utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States, to the extent such testing had the potential to demonstrate actual or potential nitrosamine contamination.
- 27.16. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of the production equipment utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States, to the extent such testing had the potential to demonstrate actual or potential nitrosamine contamination.
- 28.17. The extent of the actual and potential nitrosamine contamination of Teva's valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

#### Quality Assurance and Quality Control Activities

Commented [SH3]: To the extent relevant covered by No1 and No2.

- 29.18. Teya's SOP's/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination of valsartan API-Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in valsartan API evaluated by or purchased by Teva for use in manufacturing finished dose products for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
- 30.19. Teva's SOP's/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination of Teva's finished dose. Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Teva's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or
- 31.20. Teva's application of cGMPs in connection with the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

#### **Process Development**

- The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API.
- 33.21. Any evaluation conducted by or on behalf of Teva with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API used to manufacture finished dose products for sale in the United States.
- 34.22. Teva's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API used to manufacture finished dose products for sale in the United States.
- 35.23. Teva's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Mylan's valsartan API, used to manufacture finished dose products for sale in the United States.
- 36.24. Teva's ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API.
- Teva's ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan API.

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37-26. Teva's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Teva's valsartan finished dose.

#### Communications with Regulatory Agencies

- 38.27. The communications with any <u>United States</u> regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API. With regard to foreign regulatory authorities, as these issuescommunications such as they relate to or are reflected in regulatory inspection reports, warning letters, 483-like documents, responses to those documents, and root cause analysis for the facilities which manufactured finished dose product for sale in the United States, and communications regarding potential or actual nitrosamine contamination prior to the July 2018 recalls.
- 39.28. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's finished valsartan API. With regard to foreign regulatory authorities, as these issuescommunications such as they relate to or are reflected in regulatory inspection reports, warning letters, 483-like documents, responses to those documents, and root cause analysis for the facilities which manufactured finished dose product for sale in the United States, and communications regarding potential or actual nitrosamine contamination prior to the July 2018 recalls.
- 40-29. Teva's disclosures to <u>United States</u> regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
- 41.30. Teva's disclosures to <u>United States</u> regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan API with nitrosamines including NDMA and NDEA.
- 42.31. Teva's disclosures to <u>United States</u> regulatory authorities, including the FDA, with regard to the actual or potential contamination of Teva's valsartan finished dose with nitrosamines including NDMA and NDEA.

#### Teva's Communications with API Manufacturers and Downstream Customers

- 43.32. Teva's oral and written communications with ZHP with regard to the content/purity/contamination of ZHP's valsartan API.
- 44.33. Teva's oral and written communications with Mylan with regard to the content/purity/contamination of Mylan's valsartan API.
- 45.34. Teva's oral and written communications with its valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, -related to the Teva finished dose product manufactured for sale in the United States.
- 46-35. Teva's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the

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- contents and purity of Teva's finished dose\_<u>product manufactured for sale in the United</u> States.
- 47.36. Teva's product recall for valsartan finished dose, including who Teva communicated with, how, about what, and the retention of recalled or sequestered valsartan finished dose product manufactured for sale in the United States.
- 48-37. All credits, indemnification, refunds, and/or penalties paid or provided by or to Teva in connection with the nitrosamine contamination of valsartan <u>finished dose product manufactured for sale in the United States</u>.

#### Compliance with cGMPs

49.38. Teva's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination as it relates to the manufacture, quality assurance, quality control, and sale of Teva's API and finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

#### **Product Tracing**

- 50-39. Tracing of batches and lots of Teva's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
- 51.40. The pricing of Teva's valsartan finished dose that was ultimately sold in the United States.
- 52.41. The gross and net profits to Teva from the sale of Teva's valsartan finished dose in the United States.
- 53.42. The quantity/units of Teva's valsartan finished dose sold in the United States.
- 54.43. The Teva valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).

## Corporate Relationships

55.44. Teva's acquisitions and ownership of entities that purchased valsartan API and sold valsartan finished dose intended for use in the United States.